SUDA LTD

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ASX Release

SUDA LTD PUBLISHES SHAREHOLDER NEWSLETTER

PERTH, AUSTRALIA – 23 February 2015: SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, today published a shareholder newsletter, which has been mailed to shareholders who have requested hard copies.

Mr Stephen Carter, Chief Executive Officer of SUDA said: "The newsletter is a valuable forum to put recent news in context, to highlight upcoming events, and to set out in more detail some of the exciting assets and activities at SUDA."

"In this edition, we continue the theme of *Business Development* with an update on ongoing discussions with the pharmaceutical industry and a 'behind the scenes' chat with Mr. Nick Woolf, SUDA's Chief Business Officer. In this newsletter, we also expand on our news flow guidance for CY2015 with the inclusion of key anticipated events in relation to the progression of our pipeline of oral sprays. Furthermore, we describe the value proposition for our deal with Amherst Pharmaceuticals and the new addition to our pipeline: ZolpiMist® (zolpidem) oral spray for the treatment of insomnia."

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NOTES TO EDITORS:

About SUDA LTD

SUDA LTD (ASX: SUD) is a drug delivery company focused on oro-mucosal administration, headquartered in Perth, Western Australia. The Company is developing low-risk oral sprays using novel formulations of existing off-patent pharmaceuticals. The many potential benefits of administering drugs through the oral mucosa (ie: cheeks, tongue, gums and palate) include ease of use, lower dosage, reduced side effects and faster response time. SUDA's product pipeline includes ZolpiMist®, a first-in-class oral spray of zolpidem for insomnia. ZolpiMist® is marketed in the USA and SUDA has rights to the product outside of the Americas and South Africa. SUDA's most advanced development-stage product, ArTiMist™, is a novel sublingual malaria treatment for children. In a Phase III trial, ArTiMist™ was shown to be superior to intravenous quinine. Other products in development include oral sprays for the treatment of migraine headache, chemotherapy-induced nausea and vomiting, erectile dysfunction and pre-procedural anxiety. For more information, visit www.sudaltd.com.au

SUDA LTD

Drug delivery through the oral mucosa

Fast tracking pharmaceutical development

Our business model is to develop low-risk pharmaceuticals using novel formulations of existing drugs that are off patent. We re-formulate these drugs to provide patentable products or line extensions for existing franchises.

Increasing interest from Pharma in our OroMist oral spray technology

We were delighted to announce on 8 January 2015 the signing of our first OroMist collaboration. This deal, with Amherst Pharmaceuticals, (described on Page 4) not only secures a US partner for SUDA's SUD-002 first-in-class anti-emetic, but also strengthens our portfolio with a US-registered unique oral spray for insomnia, ZolpiMist®.

Amherst is just one of many pharmaceutical companies that recognise the opportunity for oro-mucosal delivery of drugs. We initiated our outreach to the industry 12 months ago, and have now met or interacted with 124 companies, up from 116 at the time of the AGM. Active discussions (with or without confidentiality agreements) are ongoing with 65 of these companies, up from 61 in November 2014. Our hit rate of successful conversion of initial interaction to active discussions is 52%. The number of active discussions that have advanced to due diligence or beyond has increased to 14 from 10 in November 2014.

It has been a busy start to CY2015 with one deal signed and more to come. The team continues to work hard to achieve our business development goals of securing partnerships that generate income and create significant shareholder value.

Diary Events

25-28 February 2015 – Sydney & Melbourne
Investor roadshow
The SUDA management will be meeting with brokers, shareholders and analysts

10-12 March 2015 – Paris, France
BIO-Europe Spring 2015
This is a pre-eminent international partnering event in Europe that attracts over 2,000 attendees, including business leaders from large and midsize Pharma companies, investors and other industry experts

15-18 June 2015 – Philadelphia, USA
BIO International Convention
This is the largest global industry event that attracts the biggest names in biotech, offers key networking and partnering opportunities, and provides insights and inspiration on the major trends affecting the industry

Our proprietary and patented drug delivery platform has broad potential to enhance many classes of existing drugs and we have established a rich pipeline of product candidates

Westcoast achieves underlying sales growth of 22% in Q2 FY2015

Receipts from customers for the second quarter of FY2015 were $1.9m, a quarter-on-quarter increase of 23% from the first quarter.

Excluding receipts from servicing detention centres, which provided an exceptional boost to the FY2014 results, the second quarter sales increased 22% from the same period in the previous year.

The revenue derived from detention centres has shrunk significantly in FY2015 due to the government's Operation Sovereign Borders policy. Westcoast has been investing in its new revenue drivers, including the HemoStyp® wound-healing gauze and its new Brisbane-based operations. We anticipate these opportunities adding to the growth of the business.

'…Count stars and the drops that make a lake full, no more …'

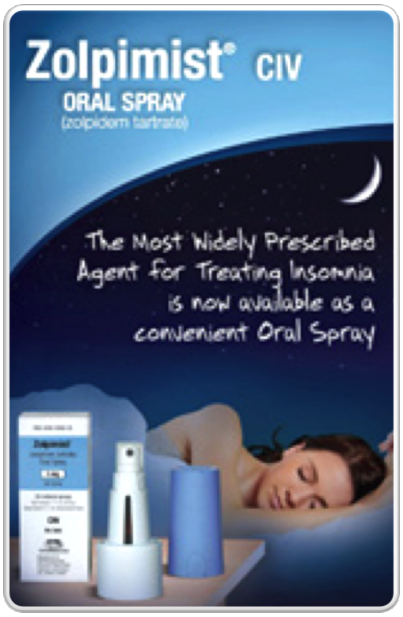
(Extracts from Franklin Pierce Adams – Lullaby)

Insomnia is a common complaint with as many as one in three experiencing difficulties in falling and/or staying asleep. Persistent insomnia is an important health burden having an adverse impact on the quality of life, occupational functioning, and psychological and mental health of the individual affected.

ZolpiMist® is a fast acting, cherry-flavoured, oral spray formulation of zolpidem tartrate (marketed as Stilnox® in tablet form), delivered over the oral mucosa in the form of a micro-mist.

One or two sprays induce drowsiness in a statistically shorter time than the tablet and it is conveniently administered without water.

In primary market research, prescribers liked the Oral Spray concept, with a more rapid onset, and the potential for middle of the night dosing recognised as clear benefits versus currently available products.



Unmet need for pre-referral anti-malarial treatments

Prompt access to effective medicine is important in the treatment of any disease, but in rural areas of sub-Saharan Africa, more often than not this is not achievable. Disease progression in paediatric malaria is rapid, with a short window of a few hours for therapeutic intervention to prevent the parasite count from escalating and becoming a medical emergency.

In rural areas where parenteral treatment is not immediately available, rectal suppositories are recommended as a pre-referral treatment for children. This approach has a number of limitations that ArTiMist™ is able to overcome.

Cultural aspects have limited the acceptance of suppositories in many African countries, and diarrhoea is an unwelcome complication, reducing the effectiveness of rectal administration.

ArTiMist™ is a convenient sublingual spray that can be administered without water by a member of the health community with minimal training.

Clinical trials have shown that a single dose of ArTiMist® can significantly reduce the parasite count within hours and can slow down the disease progression while the child and carer are on route to hospital.

ArTiMist™ represents a novel approach to pre-referral treatment, which is attracting the attention of the industry, Medicines for Malaria Venture, the WHO and other interested groups.

Multiple value-inflection points anticipated in CY2015

Anticipated Event	Guidance
Appointment of migraine Clinical Advisory Board for SUD-001	Q2 CY2015
ArTiMist™ pre-referral plan presented to Medicines for Malaria Venture and WHO	Q2 CY2015
SUD-001 pivotal development plan presented to the FDA	Q2 CY2015
Appointment of erectile dysfunction Clinical Advisory Board for SUD-003	Q2 CY2015
ArTiMist™ trade sale or out-licensing deal	H1 CY2015
SUD-003 pivotal development plan presented to the FDA	Q3 CY2015
Amherst Pharmaceuticals to manufacture commercial batches of SUD-002	CY2015
Co-development and/or product line extension deal	CY2015
Out-licensing deals for in-house pipeline of oral sprays	CY2015

We have expanded our news flow guidance for CY2015 to include not only commercial goals, but also key events in relation to the progression of our pipeline of oral sprays. These milestones will add value to the respective projects and support our partnering objectives.

A common question that arises in our discussions with pharmaceutical companies is: "What is the cost and timeframe to complete the development of SUD-00#?"

We are addressing this question. Our project management and regulatory teams, together with external clinical specialists, are putting together definitive development plans for both SUD-001 and SUD-003 (NB: Amherst is responsible for the SUD-002 plan). These plans will be presented to the FDA during CY2015 to ensure that the studies meet the requirements for a New Drug Application (NDA).

We believe, as do our lead prospective partners, that the primary positioning of our ArTiMist™ sublingual spray is for pre-referral paediatric malaria. A key value-inflection point for the project will be presenting our plan for a pivotal trial of ArTiMist™ in this setting to the Medicines for Malaria Venture, WHO and other philanthropic groups in 2Q CY2015, and securing their commitment for funding.

SUD-001 FDA meeting

There is a substantial amount of preparation required for a formal meeting with the US FDA. We are finalising a request to the FDA for a 'Type C' meeting in Q2 CY2015 to discuss the development plan for SUD-001.

The meeting request includes a synopsis of the plan and a set of questions about the sufficiency of the proposed studies to support safety and efficacy claims within a NDA. Thirty days in advance of the meeting, we are required to submit a detailed briefing package that includes the protocols of the proposed trials.

> "The Type C meeting with the FDA will strengthen our negotiating position with partners by quantifying the cost and time to get to market."

The SUD-001 development plan is designed to achieve a NDA submission in 2017 and includes several value-adding data points throughout the period. We are in discussions with several large pharmaceutical companies that are interested in collaborating on the development of SUD-001.

Our mission is to improve the health and lifestyle of the global community by providing new, high-quality, innovative, pharmaceutical products to assist in the treatment of various conditions whilst maintaining consistent growth and investment value for shareholders.

Creative deal with Amherst advances SUD-002 to market and expands our portfolio with ZolpiMist®

Our partnership with Amherst Pharmaceuticals was value adding on several fronts: firstly, we received an exclusive global licence (excluding Americas and South Africa) to ZolpiMist®, an oral spray for insomnia, registered in the USA; secondly, Amherst funds all further development of SUD-002 in the USA and SUDA is entitled to use the data generated by Amherst for approvals in other countries; and thirdly, we receive a 12% share of Amherst's income from SUD-002 in North America. It is a great deal for us.

ZolpiMist® is a significant value proposition because no further development work is required for approval in most countries. Market applications may be filed within 12 months. We have added ZolpiMist® to our business development activities and have already received approaches from companies interested to license the product in our territory.

We are not giving guidance on the financial terms for ZolpiMist® partnerships, but will highlight one comparable deal – Orexo AB received USD20m upfront for a sublingual tablet of zolpidem and an anti-histamine nasal spray. This global deal indicates the potential value of our first-in-class oral spray of zolpidem.

First patent granted for SUD-003 erectile dysfunction spray

SUDA was granted the first patent for its oral spray of sildenafil for erectile dysfunction (ED), SUD-003 or DuroMist™, in January 2015. The patent provides exclusivity until 2031 and is pending in other major jurisdictions.

> "The grant of this patent will further strengthen our negotiating position with prospective partners in the pharmaceutical industry."

Our initial proof-of-concept study of SUD-003 showed efficient absorption of sildenafil into the blood with enhanced bioavailability. Hence, SUD-003 requires less of the active drug to achieve the same therapeutic effect as the commercially available Viagra® tablets.

We have completed the development of a second-generation formulation of SUD-003, which includes flavouring, taste masking and optimal permeation characteristics that are designed to enhance further the onset of action and bioavailability.

According to primary market research in the USA, SUD-003 could capture 34% of the >USD3billion ED market if the spray achieves quicker onset of action than Viagra® tablets.

Behind the scenes: *Business Development*

The Business Development team has had a busy 12 months. We go behind the scenes with SUDA's Chief Business Officer, Nick Woolf, to understand the opportunities and challenges.

Q: How large is the business development team at SUDA?

A: "Our in-house team is just two, being myself in Perth and our European BD manager in London, Lorenza Castellon. We also work with Torreya Partners, a leading BD consultancy based in New York."

Q: What is the process for approaching pharmaceutical companies?

A: "We target high-profile business matching events such as BIO-Europe and the American BIO International Convention. These are great forums to connect with the industry and have been highly productive for us."

Q: How successful have you been in attracting companies?

A: "More successful than I expected. At the three conferences we attended in 2014, all of our time slots were filled and we had to turn down companies because the meetings couldn't be scheduled."

Q: You have 65 ongoing discussions. How do you manage such a large number?

A: "Some of the discussions are more intensive than others. Most of them are at the stage of evaluating non-confidential information on our pipeline products or our OroMist technology platform."

Q: Can you tell me more about the intensive discussions?

A: "Discussions become more intensive when formal due diligence begins. We have 14 prospective partners reviewing our data rooms under confidentiality. The interest spans the entire pipeline as well as opportunities to co-develop new sprays and product line extensions."

Q: How long does it take to get deals done?

A: "The Amherst deal took 9 months from start to finish. The general rule of thumb is 9-12 months, but some deals can take longer. There are several companies that are waiting on us to provide them with the costed development plan before they proceed to full due diligence."

Q: Why did you miss your guidance for deals in CY2014?

A: "It is inherently difficult to give guidance on events if the timing is out of our control. When we have competitive interest, then we can drive the process. With ArTiMist™, one of our lead prospective partners suspended their review to focus on Ebola. We are talking to them again now."

Q: Do we have competitive interest?

A: "Yes. There is competitive interest across several products, including ArTiMist™."

Q: Great, so when is the next deal?

A: "We anticipate multiple deals in CY2015 including ArTiMist™ and our first co-development and product line extension partnership."

Indian Trade Mission generates strong interest

SUDA was invited to join the Hon Andrew Robb AO MP, Minister for Trade and Investment, for the Australia Business Week in India (ABWI) in January 2015. ABWI was Australia's largest ever trade mission to India, with a series of events designed to enhance investment, education and tourism ties with India. There were over 400 delegates across 14 focus sectors.

SUDA's business development team was part of the delegation representing Life Sciences and Tropical Medicine. By participating, we were able to meet with senior executives from some of the largest Indian pharmaceutical companies.

The success of the trip is evident from the fact that we are signing confidentiality agreements with several companies that we met with in order to facilitate their detailed review of our products.

SUDA's Chief Business Officer, Nick Woolf, at ABWI

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